# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

COUNTY OF MONMOUTH	<b>§</b> 8	CIVIL ACTION NO.
et al.	§	2:23-cv-21001-MCA-MAH
	§	
<b>v.</b>	§	
	§	
Apotex Inc. et al.	§	

# JOINT PROPOSED DISCOVERY PLAN

1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

See Exhibit 1.

2. Set forth a brief description of the case, including the causes of action and defenses asserted.

### **Plaintiffs' Position:**

The plaintiffs and putative class representatives in this action, County of Monmouth and Ohio Carpenters' Health Fund (collectively, "Plaintiffs") are third-party payors ("TPPs") that allege they overpaid for metformin-containing drugs ("MCDs") that were adulterated with nitrosamines, which are alleged to be genotoxic and carcinogenic (not just those recalled or nitrosamines above an eventual FDA interim limit, as Defendants suggest below). Defendants Teva Pharmaceuticals USA, Inc., Actavis Pharma, Inc., Actavis LLC, Emcure Ltd., Heritage Pharmaceuticals, Inc., d/b/a Avet Pharmaceuticals Inc., Granules USA, Inc., Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, Avkare, Inc., and Alkem Laboratories, LLC (collectively, "Defendants") manufacture MCDs. MCDs are oral antihyperglycemic drugs used as first-line therapy for type 2 diabetes.

Plaintiffs filed their First Amended Class Action Complaint (the "FAC," ECF No. 87) on February 21, 2024. The FAC brings Plaintiffs' allegations, and the Defendants against which they assert their allegations, completely into line with the operative complaint in a parallel action pending before this Court, *In re. Metformin Marketing and Sales Practices Litig.*, 2:20-cv-2324 (D.N.J.) ("Metformin I"). It is the position of Plaintiffs and the plaintiffs in Metformin I that Plaintiffs should be brought into Metformin I through either amendment of the Metformin I complaint, or Fed. R. Civ. P. 24 intervention, or Fed. R. Civ. P. 42 consolidation.

The claims and defenses asserted in this matter accordingly are identical to the claims and defenses asserted in Metformin I. These include causes of action for breach of express warranties, breach of implied warranties of merchantability, fraud, negligent misrepresentation and omission, violation of state consumer protection laws, unjust enrichment, negligence and negligence per se.

### **Defendants' Position:**

This litigation as presently styled in Plaintiffs' First Amended Class Action Complaint ("FAC"), asserts claims on behalf of two Plaintiffs County of Monmouth and Ohio Carpenters' Health Fund (collectively, "Plaintiffs") are alleged to be TPPs, and seek to represent a putative nationwide class of TPPs that paid or reimbursed payment for certain MCDs sold in the United States that were allegedly adulterated, misbranded, or unapproved due to the presence of N-nitrosodimethylamine ("NDMA") in excess of the Acceptable Daily Intake ("ADI") limit.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Plaintiffs original Complaint, filed on October 9, 2023 (ECF No. 1), asserted claims on behalf of the two TPPs as well as two consumer plaintiffs, Carla Major and Jacqueline Harris, and against the following Defendants: Apotex Corp. ("Apotex"), Lupin Pharmaceuticals, Inc. ("Lupin"), Actavis Pharma, Inc., Actavis LLC, and Teva Pharmaceuticals USA, Inc. ("Teva"); Heritage Pharmaceuticals, Inc. (d/b/a Avet Pharmaceuticals Inc.) and Granules USA, Inc. ("Granules"); Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Inc., and AvKARE, LLC (improperly named AvKARE, Inc.) ("Amneal"); Ascend Laboratories, LLC ("Ascend"), Nostrum Laboratories, Inc. and Nostrum Pharmaceuticals LLC (collectively, "Nostrum"), CVS Health

Plaintiffs allege that the presence of NDMA in Defendants' MCDs resulted from their manufacture in a "non-cGMP compliant manner" and rendered them "non-bioequivalent" and "non-therapeutically equivalent" to the Reference Listed Drugs ("RLDs"), therefore breaching Defendants' "express warranties of sameness," and rendering Defendants' MCDs "essentially worthless" with "no market value." Thus, Plaintiffs allege they "have been injured and suffered damages in the amount of the purchase price for their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases[.]" Plaintiffs assert the following causes of action: breach of express and implied warranty; fraud; negligent misrepresentation and omission; negligence and negligence per se; violation of several state consumer protection, legal remedies, and unfair competition statutes; and unjust enrichment under certain state laws.

Defendants deny any and all liability and have moved to dismiss the FAC. [See ECF No. 92]. Defendants' pending motion asserts Plaintiffs' claims should be dismissed because: (i) Plaintiffs' claims are partially or wholly barred by the statute of limitations; (ii) Plaintiffs lack standing; (iii) Plaintiffs' claims are preempted and subject to the primary jurisdiction doctrine; (iv) Plaintiffs' claims are subsumed or barred by applicable state law; (v) Plaintiffs fail to state a claim for breach of express warranty; (vi) Plaintiffs fail to state a claim for breach of implied warranties; (vii) Plaintiffs fail to state fraud claims; and (viii) Plaintiffs fail to state common law claims—

Corporation, and Rite-Aid Corporation. Plaintiffs' FAC has dropped all claims asserted on behalf of the two consumer plaintiffs, Carla Major and Jacqueline Harris, and against the Apotex, Lupin, and Nostrum defendants. Additionally, while Plaintiffs' FAC appears to attempt to limit Plaintiffs' at-issue payments to only payments for MCDs that were recalled or otherwise found to contain NDMA above ADI limits in the 2020 Valisure Citizen Petition, their class allegations still seek to certify a nationwide class consisting of "[a]ll individuals and entities in the United States and its territories and possessions who paid any amount of money for a [MCD] . . . that was manufactured, distributed, or sold by any Defendant." [See ECF No. 87, ¶ 315].

including negligent misrepresentation, negligence, negligence per se, and unjust enrichment—and state consumer protection law claims. Defendants' Motions to Dismiss the FAC is pending before the Court, returnable on May 6, 2024.

Defendants further deny Plaintiffs' allegations, including that the subject MCDs were defective in any manner, or that they were non-bioequivalent or non-therapeutically equivalent to the RLD. Defendants deny that the subject MCDs were not manufactured in compliance with cGMPs, and deny that the products or any impurities allegedly contained therein were genotoxic or carcinogenic to humans or rendered the subject MCDs worthless or without market value. Defendants also assert that Plaintiffs' putative class is not certifiable based on the requirements set forth by Fed. R. Civ. P. 23 and interpreting case law. Defendants assert that Plaintiffs' claims are barred because the methods, standards, and techniques used in designing, manufacturing, marketing, distribution and/or selling the MCDs at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed. Defendants also maintain that all acts of Defendants at the time of the alleged design, manufacture, and/or sale of the product at issue were in conformity with the state-of-the-art of the relevant industry at all relevant times, including, but not limited to, all standards set by United States Pharmacopeia ("USP"). In addition, Defendants assert any and all defense doctrines available to them under applicable law, including, but not limited to: express and implied preemption under federal law; any and all provisions of the UCC regarding disclaimers, limitations of implied warranties, lack of reliance, lack of notice, and lack of privity; state of the art compliance with industry customs and practice, and all applicable laws and regulations; superseding causes or negligence of third parties; failure to mitigate damages; assumption of risk; learned intermediary, sophisticated purchaser, and/or sophisticated user doctrines; comparative

negligence, apportionment of damages, contribution, indemnity, and/or setoff; and any and all other defenses and/or liability exemptions afforded to Defendants under applicable state law.

Though similar in the nature of its allegations, this case differs from *In re Metformin Marketing and Sales Practices Litigation*, No. 2:20-cv-2324 (D.N.J.) ("*In re Metformin*"), in that it was filed more than three years after the Food and Drug Administration ("FDA") announced the voluntary recalls of certain MCDs and involves new putative class representative plaintiffs, one of whose claims implicates new state substantive law. Plaintiffs have provided no justification as to why they did not file their claims alongside the plaintiffs in *In re Metformin*.

The parties have been discussing the potential consolidation for discovery and pretrial purposes only of this matter with *In re Metformin*. Consistent with those discussions, Defendants prepared and provided to Plaintiffs a proposed stipulation on March 27, 2024, which would immediately consolidate this matter with *In re Metformin* for discovery and pretrial purposes only, amend the case schedule in *In re Metformin* to permit time to take necessary discovery of the new TPPs and any related non-party discovery, and permit the filing of a Third Amended Consolidated Economic Loss Class Action Complaint after the Court issues decisions on the pending motion to dismiss the FAC in this matter<sup>2</sup>—thereby obviating the need for additional briefing of a motion to amend the pleadings in *In re* Metformin.

Plaintiffs, however, requested that Defendants withdraw their motion to dismiss the FAC and brief any dismissal issues in the context of a motion for leave to amend the Second Amended Complaint in *In re Metformin*. When Defendants declined to withdraw their pending motion explaining the inefficiencies and prejudice in Plaintiffs' proposal, Plaintiffs filed their Motion for

<sup>&</sup>lt;sup>2</sup> The stipulation will also permit the consolidation of another related matter (*Marcia E. Brice v. Amneal Pharmaceuticals, Inc.*, et al., No. 20-13728) after a ruling is issued as to the pending motion to dismiss in that matter.

Leave to Amend Complaint, or in the First Alternative to Intervene, or in the Second Alternative to Consolidate on March 29, 2024, in *In re Metformin*. [ECF No. 434 (*In re Metformin*)]. Defendants filed a letter request with the Court on April 2, 2024, requesting that Plaintiffs' Motion be stricken or held in abeyance as it was filed without prior approval of the Court and the parties had not concluded their negotiations concerning the proposed stipulation that would moot the need for Plaintiffs' Motion. [ECF No. 94 (*County of Monmouth*) and ECF No. 435 (*In re Metformin*). Plaintiffs filed a letter in response to Defendants' letter also on April 2, 2024. After reviewing both submissions, the Court granted Defendants' request on April 3, 2024. [ECF No. 437 (*In re Metformin*)]. The parties continue to meet and confer about the logistics of consolidating this matter with *In re Metformin* for discovery and pretrial purposes and will advise the Court on or before May 2, 2024.

### 3. Have settlement discussions taken place?

No.

### 4. The parties have met pursuant to Fed. R. Civ. P. 26(f).

The parties met and conferred on March 19, 2024, and continue to communicate via email.

# 5. The parties <u>have not</u> exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefore.

### **Plaintiffs' Position:**

Plaintiffs will serve their initial disclosures within fourteen days of the filing of this report. Plaintiffs ask that all Defendants amend or update their initial disclosures within fourteen days of this report to account for the additional parties in Metformin II.

### **Defendants' Position:**

Defendants agree with Plaintiffs proposal that they serve their initial disclosures within fourteen days of the filing of this report, *i.e.*, **April 19, 2024**. Defendants in this matter have already provided initial disclosures in *In re Metformin* and discovery in that matter is proceeding apace. Defendants have agreed to consolidation of this matter for discovery and pretrial purposes. Thus, Plaintiffs will have the benefit of Defendants' prior discovery served in *In re Metformin*, including Defendants initial disclosures. Defendants agree to amend their initial disclosures previously served in *In re Metformin*, if warranted, by **May 1, 2024**.

6. Explain any problems in connection with completing the disclosures required by Fed R. Civ. P. 26(a)(1).

*See* response to item 5.

7. The parties <u>have not</u> filed disclosures of third-party litigation funding. See Local Civil Rule 7.1.1.

Plaintiffs are aware of their obligation under Local Civil Rule 7.1.1 and will file disclosures under that Rule if and when required to do so. Currently, Plaintiffs are unaware of any disclosures that need to be filed under that Rule.

None of the Defendants in this case receive third-party litigation funding.

8. The parties <u>have</u> conducted discovery other than the above disclosures.

### **Plaintiffs' Position:**

Plaintiffs are preparing discovery demands in this action. Plaintiffs and Defendants currently are discussing the means of consolidating this action and Metformin I, and the scope of consolidation including as it pertains to discovery but have not yet reached agreement.

### **Defendants' Position:**

Defendants served interrogatories and requests for production of documents on Plaintiffs on March 28, 2024. Pursuant to the agreement reached in *In re Metformin*, parties have 45 days to respond to written discovery, which would make Plaintiffs' responses to Defendants' initial written discovery due on May 13, 2024. In addition, Defendants have agreed to consolidate this matter with *In re Metformin* for discovery and pretrial purposes. Defendants have already engaged in significant discovery in In re Metformin, including initial disclosures, written responses to expansive document requests and interrogatories, and ongoing document productions, to which Plaintiffs will have access upon consolidation. Plaintiffs indicate above that they are preparing discovery demands, but have not yet disclosed to Defendants what, if any, additional discovery they believe is warranted beyond the extensive discovery that is ongoing in *In re Metformin*. Plaintiffs have also indicated that it is their position that they are entitled to additional discovery, "unless and until they are brought into Metformin I via amendment of the Metformin I complaint." See Section 9(b) below. As explained throughout, Defendants have agreed to the consolidation of this matter with In re Metformin for discovery and pretrial purposes, and that no additional discovery of Defendants is warranted beyond the expansive discovery that is already being conducted in In re Metformin.

### 9. Proposed joint discovery plan:

### (a) Discovery is needed on the following subjects:

### **Plaintiffs' Position:**

Discovery in this matter will be substantially identical to the discovery already underway in Metformin I. The parties should accordingly work in good faith to avoid unnecessarily duplicative discovery between this action and discovery taken and underway in Metformin I.

To that end, subject to the protective order in Metformin I and any protective order entered in this action, (i) Defendants shall produce or shall be deemed to have produced all documents produced in Metformin I, and shall continue to produce or be deemed to produce additional documents as they produce them in Metformin I; (ii) Defendants shall serve or shall be deemed to have served all transcripts and exhibits for depositions taken in Metformin I, and shall continue to serve or be deemed to serve additional transcripts and exhibits as depositions are taken in Metformin I, and (iii), as to any additional depositions that are noticed in Metformin I or in this action, the parties shall confer regarding the "cross-noticing" of depositions in order to avoid unnecessary duplication.

Beyond the discovery already taken or being taken in Metformin I, the parties anticipate limited additional discovery relating to the Plaintiffs and unique defenses in this case, and to certain of Defendants' products that are within the scope of the allegations in Metformin I and the present case but were not subject to discovery in Metformin I.

### **Defendants' Position:**

Defendants agree that the discovery in this matter of Plaintiffs will be similar to that conducted in *In re Metformin*, but not identical. These are two new Plaintiffs who have not engaged in any discovery to date. To the extent any of Plaintiffs' claims survive the pending motion to dismiss, Defendants anticipate that discovery may be needed on one or more of the following subjects: (1) product identification by Plaintiffs (including whether Plaintiffs can trace the MCDs they paid or reimbursed for to a lot manufactured and/or sold by one or more of the Defendants in the United States, and whether Plaintiffs can establish that the MCDs they paid or reimbursed payment for were contaminated and recalled); (2) general causation and related threshold questions as to the viability of Plaintiffs' claims (including whether the amounts of nitrosamine impurity

allegedly contained within the MCDs can generally cause specific cancers in humans, and whether the alleged nitrosamine impurity causes the MCDs to be non-bioequivalent to their respective RLDs); (3) class certification; and (4) merits discovery, including but not limited to discovery pertaining to specific Plaintiffs' claims of liability and damages. Defendants have served an initial set of requests for production and interrogatories on Plaintiffs.

Defendants have already engaged in significant discovery in *In re Metformin*, including initial disclosures, written responses to expansive document requests and interrogatories, and ongoing document productions, all of which Defendants agree may be deemed to be produced to Plaintiffs in this matter, once all counsel are subject to the Stipulated Discovery Protective Order ("Stipulated DCO") entered in In re Metformin. [ECF No. 154 (In re Metformin)]. Plaintiffs' position above mentions production of transcripts and exhibits from depositions, but no depositions have taken place in In re Metformin. Although Defendants asked during their Rule 26(f) conference, Plaintiffs did not identify any additional discovery of Defendants that would be needed beyond that which is already underway in *In re Metformin* and Defendants submit that no additional discovery of Defendants is warranted. Plaintiffs' position above now mentions taking discovery about "certain of Defendants' products that are within the scope of the allegations in Metformin I and the present case but were not subject to discovery in Metformin I." Defendants understand that Plaintiffs intend to seek to revisit this Court's prior denial of Plaintiffs' request to take discovery from Teva concerning Teva's Extended-Release products and associated ANDAs that were not part of the 2020 recalls, and related denial of Plaintiffs' Motion for Reconsideration in In re Metformin. See ECF Nos. 382 and 407. Teva objects to any efforts by Plaintiffs to revisit this Court's prior discovery orders, all of which were entered after fulsome submissions to the Court and extensive argument.

(b) Whether Discovery <u>should</u> be conducted in phases or be limited to particular issues.

### **Plaintiffs' Position:**

As Defendants observe, the Court rejected a phased approach to discovery in Metformin I. See Metformin I, ECF No. 266. Plaintiffs agree with Defendants that the Court should not revisit those issues now. Plaintiffs reserve their right to raise with the Court any scheduling and discovery issues under this Court's procedures.

As to the discovery issues raised by Defendants below, including product scope and relevant time period, it is Plaintiffs' position that, unless and until they are brought into Metformin I via amendment of the Metformin I complaint, they are entitled to additional discovery in this action.

### **Defendants' Position:**

In prior submissions to the Court in *In re Metformin*, Defendants proposed that discovery in that matter be conducted in phases, including appropriate motion practice occurring at the conclusion of each phase to the extent necessary, which Defendants submitted to the Court would result in a more efficient and orderly discovery process. [*See* ECF No. 264 (*In re Metformin*). Under Defendants' proposal, certain important threshold issues would be resolved early in the case, which would result in a significant narrowing of issues. One such threshold issue was the scope of Metformin products at issue in the litigation, which also implicated the relevant time period for discovery. At that time the Court declined to adopt Defendants' phased proposal for scheduling in *In re Metformin*. [*See* ECF No. 266 (*In re Metformin*). Given the Court has already considered this issue in *In re Metformin*, the Defendants are not seeking to fully revisit those issues at this time. Defendants, however, reserve their rights to raise with the Court any scheduling and discovery issues under this Court's procedures, including any appropriate phasing should that

become warranted to further promote and increase efficiencies or to decrease prejudice to Defendants.

Although the Court declined to adopt Defendants' phased approach to scheduling in In re Metformin, certain threshold discovery issues, including product scope and relevant time period, both of which would significantly impact the proper scope of discovery from Defendants, were raised with the Court for resolution, and the Court resolved those issues with rulings limiting the scope of discovery Plaintiffs were seeking from Defendants. [See ECF Nos. 322, 367, 372, 380, 381, 382, and 407 (In re Metformin)]. Despite the foregoing, and Plaintiffs' request that this matter be consolidated with In re Metformin, Plaintiffs have now indicated an intent to seek discovery from Defendants in this case about "certain of Defendants' products that are within the scope of the allegations in Metformin I and the present case but were not subject to discovery in Metformin I." As indicated in Section 9 above, Defendants understand that Plaintiffs intend to seek to revisit this Court's prior denial of Plaintiffs' request to take discovery from Teva concerning Teva's Extended-Release products and associated ANDAs that were not part of the 2020 recalls, and related denial of Plaintiffs' Motion for Reconsideration in In re Metformin. [See ECF Nos. 382 and 407 (In re Metformin)]. Teva objects to any efforts by Plaintiffs to revisit this Court's prior discovery orders, all of which were entered after fulsome submissions to the Court and extensive argument. Should Plaintiffs seek to revisit these, or other prior discovery rulings of the Court, Defendants will be forced to ask now that the Court revisit its prior ruling in *In re Metformin* concerning a phased schedule.

# (c) Proposed schedule:

(1) Fed. R. Civ. P. 26 Disclosures.

See item 5.

# (2) E-Discovery conference pursuant to L. Civ. R. 26.1(d).

### **Plaintiffs' Position:**

The parties generally discussed discovery, including ESI, during their March 19, 2024 Rule 26(f) conference, and have agreed that the Stipulated Electronic Discovery Protocol entered in *In re Metformin* will govern electronic discovery in this case. Unless and until they are brought into Metformin I as plaintiffs via amendment of the Metformin I complaint, Plaintiffs reserve their rights to negotiate search terms, custodians, and a TAR protocol in this action. Plaintiffs anticipate conducting additional conferences with Defendants concerning their electronic discovery, including custodians, non-custodial documents, and search terms or other means of searching Plaintiffs' ESI.

### **Defendants' Position:**

The parties generally discussed discovery, including ESI, during their March 19, 2024 Rule 26(f) conference, and have agreed that the Stipulated Electronic Discovery Protocol entered in *In re Metformin* will govern electronic discovery in this case. Defendants have already negotiated search terms, custodians, and a TAR protocol to the extent applicable to each Defendant in *In re Metformin* and therefore do not anticipate a need to revisit those issues with Plaintiffs. Defendants anticipate conducting additional conferences with Plaintiffs concerning their electronic discovery, including custodians, non-custodial documents, and search terms or other means of searching Plaintiffs' ESI.

### (3) Service of initial written discovery.

### **Plaintiffs' Position:**

As the parties have already had their Rule 26(f) conference, Plaintiffs intend to immediately serve discovery upon Defendants and certain third parties.

### **Defendants' Position:**

Following the parties' Rule 26(f) conference, and to facilitate the parties' negotiations concerning consolidation and scheduling, on March 28, 2024, Defendants served an initial set of requests for production and interrogatories on Plaintiffs. Defendants may serve any additional written discovery on or before **September 16, 2024**. Given the expansive discovery already underway by Defendants in *In re Metformin*, Defendants agreement to this matter being consolidated with *In re Metformin* for discovery and pretrial purposes, and Plaintiffs failure to identify any additional discovery that would be warranted, Defendants do not believe any further written discovery of Defendants should be served. Should Plaintiffs identify limited specific non-duplicative additional discovery, Defendants stand ready to meet and confer with Plaintiffs regarding any such requests.

### (4) Interrogatories.

**Plaintiffs' Position:** Plaintiffs may serve 25 interrogatories on each Defendant on or before August 15, 2024. The presumptive deadline to respond shall be 45 days.

### **Defendants' Position:**

Defendants may serve interrogatories on Plaintiffs limited to 25 single questions including subparts, on or before **September 16, 2024**. The presumptive deadline to respond shall be 45 days. Given the expansive discovery already underway by Defendants in *In re Metformin*, Defendants agreement to this matter being consolidated with *In re Metformin* for discovery and pretrial purposes, and Plaintiffs failure to identify any additional discovery that would be

warranted, Defendants do not believe any further written discovery of Defendants should be served. Should Plaintiffs identify limited specific non-duplicative additional discovery, Defendants stand ready to meet and confer with Plaintiffs regarding any such requests.

## (5) Depositions to be taken by each party.

### **Plaintiffs' Position:**

Plaintiffs reserve their right to seek depositions in excess of 10 depositions on each Defendant given the number of defendants and third parties. Any dispute concerning the number of depositions shall be raised promptly with the Court if the parties reach an impasse, or no later than **October 30, 2024.** 

### **Defendants' Position:**

Consistent with the scheduling order entered in *In re Metformin*, the parties shall meet and confer prior to the start of depositions to discuss the number of depositions to which each side will be entitled, bearing in mind both the limits imposed by Fed. R. Civ. P. 30(a) and the parties' obligation to minimize redundancy and maximize efficiency. Any dispute concerning the number of depositions shall be raised promptly with the Court, only after the parties have thoroughly met and conferred, by way of a joint letter to be filed on or before **October 30, 2024.** 

### (6) Motions to Amend

### **Plaintiffs' Position:**

Any motions to amend or to add parties or amend pleadings, whether by amended or thirdparty complaint, must be filed by May 2, 2024 or 30 days after the Court rules on any motion **to dismiss**. In the event the parties reach agreement on amendment/consolidation with Metformin I, this deadline can and should be extended beyond May 2, 2024.

# **Defendants' Position:**

Any motions to amend or to add parties or amend pleadings, whether by amended or third-party complaint, must be filed by **May 2, 2024**. Any such motion must include a red-lined draft of the proposed amended pleading that highlights any proposed changes.

### [Items 9(c)(7)-(11)]

### Plaintiffs' Position (Items 9(c)(7)-(11)):

Defendants' proposal for a uniform extension of all current deadlines from *In re Metformin* by the same period of time does not contemplate or address the need to complete fact discovery and use that discovery for purposes of filing class certification motions and related expert reports. Indeed, Defendants' schedule would require Plaintiffs to file class certification and have their experts complete their reports approximately two weeks after fact discovery is scheduled to be completed. Defendants' proposal clearly does not provide sufficient time for Plaintiffs and their experts to utilize the information obtained, whereas Plaintiffs' proposal provides Plaintiffs and their experts the time necessary to review and utilize the discovery obtained while accounting for the end-of-year holidays. Thus, in addition to the foregoing, and consistent with the Court's prior orders entered in *In re Metformin*, Plaintiffs propose the following deadlines.

- (7) All third-party discovery, including the service of subpoenas, shall be served by **September 30, 2024**.
- (8) The deadline for substantial completion of the parties' document productions is 90 days before the close of fact discovery (i.e., **September 16, 2024**).

- (9) Fact discovery to be completed by **December 16, 2024.**
- (10) Discovery disputes (other than those arising during depositions, or any other outstanding discovery not completed by September 16, 2024) shall be brought to the Court's attention no later than **November 16, 2024**.
- (11) Class Certification The parties agree to coordinate the schedule for Plaintiffs' class certification motion in this matter with the schedule for Plaintiffs' class certification motion in *In re Metformin*. Plaintiffs propose the following amended schedule:
  - (a) Plaintiffs shall prepare and serve on Defendants any motion for class certification and accompanying expert reports pertaining to class certification, by **February 14, 2025**.
  - (b) Defendants shall depose any Plaintiffs' expert witnesses pertaining to class certification by or before **March 14, 2025**.
  - (c) Defendants shall prepare and serve on Plaintiffs any opposition to class certification and accompanying expert reports and Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification by **April 14**, **2025**.
  - (d) Plaintiffs shall depose Defendants' expert witnesses pertaining to class certification by or before May 14, 2025.
  - (e) Plaintiffs shall prepare and serve on Defendants any reply in support of any class certification motion, opposition to any Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification, and Rule 702 motions to exclude Defendants' expert witnesses pertaining to class certification, by or before **June 16, 2025**.
  - (f) Defendants shall prepare and serve on Plaintiffs their replies in support of any Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification and opposition to any rule 702 motions to exclude Defendants' expert witnesses pertaining to class certification, by or before **July 16, 2025**.
  - (g) Plaintiffs shall prepare and serve on Defendants their replies in support of any Fed. R. Evid. motion to exclude Defendants' expert witnesses pertaining to class certification, by or before **August 15, 2025**.
  - (h) By or before August 29, 2025, Plaintiffs' counsel shall assemble all motion papers and exhibits regarding class certification and file them on the docket. Plaintiffs' counsel also shall provide two (2) courtesy copies of all motion papers to the Honorable Madeline C. Arleo, U.S. D.J.

### **Defendants' Position (Items 9(c)(7)-(11)):**

In addition to the foregoing, and consistent with the Court's prior orders entered in *In re Metformin*, no motions are to be filed without prior written permission from this Court.

Defendants do not agree to the proposed schedule dates outlined by Plaintiffs above, because the dates they propose do not seek a uniform extension of all current deadlines from *In re Metformin* by the same period of time. Thus, Plaintiffs proposal deviates from the periods of time between deadlines that were ultimately entered by this Court in *In re Metformin* and which had been heavily negotiated when the case schedule was first entered. In contrast, Defendants' proposed dates seek a uniform extension across the current dates set in *In re Metformin*, so that the schedule for this case may completely align with an amended schedule for *In re Metformin*. For the avoidance of doubt, it is Defendants position that their proposed schedule herein should be adopted as an amended schedule in *In re Metformin*, such that the two cases will be governed by the same schedule. For ease of reference and discussion, Defendants have included as Appendix A, a chart showing the deadlines from the current scheduling order in *In re Metformin*, Plaintiffs' proposed deadlines in this submission, and Defendants' proposed deadlines in this submission.

- (7) All third-party discovery, including the service of subpoenas, shall be served by **September 15, 2024**.
- (8) The deadline for substantial completion of the parties' document productions is 90 days before the close of fact discovery (i.e., October 16, 2024).
- (9) Fact discovery to be completed by **January 16, 2024.** No fact discovery is to be issued or engaged in beyond that date, except upon application and for good cause shown.
- (10) Discovery disputes (other than those arising during depositions) shall be brought to the Court's attention no later than **October 30, 2024**. Consistent with the prior orders entered in *In re Metformin*, the Court will not consider any discovery dispute (other than those arising during depositions) brought to its attention after this date. If an

unresolved dispute arises at a deposition, then the parties shall contact the Chambers of the Honorable Michael A. Hammer, U.S.M.J. for assistance during the deposition. Failure to contact Judge Hammer to intervene in a deposition dispute, before adjourning or completing the deposition, will constitute waiver of the right to seek relief for that deposition dispute.

- (11) Class Certification The parties agree to coordinate the schedule for Plaintiffs' class certification motion in this matter with the schedule for Plaintiffs' class certification motion in *In re Metformin*. The parties propose the following amended schedule:
  - (a) Plaintiffs shall prepare and serve on Defendants any motion for class certification and accompanying expert reports pertaining to class certification, by January 31, 2025.
  - (b) Defendants shall depose any Plaintiffs' expert witnesses pertaining to class certification by or before **March 17, 2025**.
  - (c) Defendants shall prepare and serve on Plaintiffs any opposition to class certification and accompanying expert reports and Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification by **April 16**, **2025**.
  - (d) Plaintiffs shall depose Defendants' expert witnesses pertaining to class certification by or before May 16, 2025.
  - (e) Plaintiffs shall prepare and serve on Defendants any reply in support of any class certification motion, opposition to any Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification, and Rule 702 motions to exclude Defendants' expert witnesses pertaining to class certification, by or before **June 16, 2025**.
  - (f) Defendants shall prepare and serve on Plaintiffs their replies in support of any Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification and opposition to any rule 702 motions to exclude Defendants' expert witnesses pertaining to class certification, by or before **July 16, 2025**.
  - (g) Plaintiffs shall prepare and serve on Defendants their replies in support of any Fed. R. Evid. motion to exclude Defendants' expert witnesses pertaining to class certification, by or before **July 30, 2025**.
  - (h) By or before **August 1, 2025**, Plaintiffs' counsel shall assemble all motion papers and exhibits regarding class certification and file them on the docket. Plaintiffs' counsel also shall provide two (2) courtesy copies of all motion papers to the Honorable Madeline C. Arleo, U.S. D.J.

- (11) **Experts** The parties agree to coordinate the schedule for merits expert reports in this matter with the schedule for merits expert reports in *In re Metformin*. The parties propose the following amended schedule:
  - (a) All affirmative expert reports shall be delivered by [TO BE DETERMINED]. Any such report is to be in the form and content as required by Fed. R. Civ. P. 26(a)(2)(B).
  - **(b)** All responding expert reports shall be delivered by **[TO BE DETERMINED]**. Any such report is to be in the form and content as required by Fed. R. Civ. P. 26(a)(2)(B).
  - (c) Expert discovery, including the depositions of any expert witnesses, shall be completed on or before [TO BE DETERMINED].
  - (d) No expert shall testify at trial as to any opinions or base those opinions on facts not substantially disclosed in his or her report.
  - (12) Dispositive motions to be filed on or before [TO BE DETERMINED].

### **Plaintiffs' Position:**

Except as otherwise set forth as to class certification, Plaintiffs agree with Defendants' position that no other motions are to be filed without prior written permission from this Court.

### **Defendants' Position:**

Consistent with the Court's orders entered in *In re Metformin*, no motions are to be filed without prior written permission from this Court. All dispositive motions must first be subject to a dispositive motion pre-hearing. Discovery must be completed prior to the filing of a dispositive motion. These prerequisites must be met before any motions are filed and the motions will be returned if not met. All calendar or dispositive motions, if permitted, shall comply with Local Civil Rules 7.1(b) and 56.1.

(c) Set forth any special discovery mechanism or procedure requested.

None.

- (d) A pretrial conference may take place on [TO BE DETERMINED].
- (e) Trial date: [TO BE DETERMINED] (Jury Trial).

# 10. Do you anticipate any special discovery needs (i.e. videotape/telephone depositions, problems with out-of-state witnesses or documents, etc)?

Yes. Several witnesses, including the Plaintiffs and several of Defendants' witnesses, reside outside New Jersey and, in certain instances, outside the country. The parties will meet and confer to prepare a separate deposition protocol addressing the needs for the depositions of these witnesses, including for Defendants the same witnesses in *In re Metformin*, addressing, without limitation, compliance with any procedures prescribed under the Hague Convention to depose witnesses located outside of the United States and procedures for any depositions to be conducted virtually on the Zoom platform.

# 11. Do you anticipate any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced?

No. A Stipulated Electronic Discovery Protocol has been entered in *In re* Metformin (ECF No. 183) ("Stipulated ESI Protocol"). The parties agree to be bound by the Stipulated ESI Protocol for this matter and will, should it be necessary, file a stipulation on the docket in this case to memorialize this agreement.

# 12. Do you anticipate entry of a Discovery Confidentiality Order? See L.Civ.R. 5.3(b) and Appendix S.

Yes. A Stipulated Discovery Protective Order of Confidentiality has been entered in *In re Metformin* (ECF No. 154) ("Stipulated DCO"). The parties agree to be bound by the Stipulated DCO for this matter and will, should it be necessary, file a stipulation on the docket in this case to memorialize this agreement.

### 13. Do you anticipate any discovery problem(s) not listed above? Describe.

Not at this time. If any discovery problems are later identified the parties will meet and confer and, if necessary, promptly raise those issues with the Court.

14. State whether this case is appropriate for voluntary arbitration (pursuant to Local Civil Rule 201.1 or otherwise) or mediation (pursuant to Local Civil Rule 301.1 or otherwise). If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition or dispositive motions, etc.).

This case is not appropriate for arbitration because Plaintiffs seek in excess of \$150,000. Given the early stage of this litigation, the Parties believe arrangements for mediation or other alternative dispute resolution may be more appropriate at a later time after a ruling on Defendants' Motion to Dismiss the First Amended Complaint, and the completion of certain discovery.

## 15. Is this case appropriate for bifurcation?

### **Plaintiffs' Position:**

No. Plaintiffs reserve their right to request that the Court consolidate this case with Metformin I for trial and other purposes.

### **Defendants' Position:**

Defendants agree that this matter may be consolidated with the *In re Metformin* matter for purposes of discovery and pretrial proceedings only. This is consistent with the Court's September 30, 2020, Order [ECF No. 76 (Civil Action No. 20-02324)] in *In re Metformin*, which consolidated eight putative class actions for discovery and pretrial purposes only, and which Order provides that any request for consolidation for trial should be made upon formal motion. This is also consistent with the Court's consolidation for discovery and pretrial purposes only of the *Marcia Brice v. Amneal Pharmaceuticals, Inc.* and *Walmart Stores, Inc.*, Civil Action No. 2:20-cv-13728

("Brice") [ECF No. 12], Ronald Worthen v. Avkare Inc., and Amneal Pharmaceuticals, Inc., Civil Action No. 2:20-cv-14052 ("Worthen") [ECF No. 6], and most recently the Michael Hann v. Amneal Pharmaceuticals of New York LLC, Civil Action No. 2:23-cv-22902 ("Hann") [ECF No. 6] matters with In re Metformin. Defendants do not agree that this matter, or any of the prior matters that have been consolidated for discovery and pretrial purposes only in In re Metformin, should be consolidated for trial.

**16.** An interim status/settlement conference (with clients in attendance) should be held in **[TO BE DETERMINED].** 

### **Plaintiffs' Position:**

Plaintiffs and Defendants are discussing a stay to the briefing of Defendant's motion to dismiss (ECF No. 92), or, alternatively, an extension of Plaintiffs' time to oppose the motion to dismiss until after the Court determines whether Metformin II should be consolidated into Metformin I. Plaintiffs believe a stay is appropriate and will conserve judicial resources because amendment of the Metformin I complaint to add the parties in Metformin II may affect whether some of Plaintiffs' claims "relate back" to Metformin I under Fed. R. Civ. P. 15(c), and consequently will affect that the arguments the parties raise, and the Court decides, on the motion to dismiss. At the Rule 16 Scheduling Conference, the parties anticipate discussing the briefing schedules for the motions pending before the Court.

### **Defendants' Position:**

Defendants request that the Court schedule status conferences approximately every 90 days or as may be appropriate in light of any request by a party or scheduling or discovery disputes submitted to the Court for resolution.

The parties are, as directed by the Court, continuing to negotiate a consolidation and scheduling stipulation. Plaintiffs have requested that Defendants agree to a stay or an extension of briefing deadlines on Defendants' pending motion to dismiss, until after the issue of consolidation is resolved. Defendants are considering Plaintiffs request, and related proposals, including issues concerning the schedule to govern both this matter and *In re Metformin*, as well as Plaintiffs' position on additional discovery and anticipate further meet and confers on these issues. Defendants look forward to discussing this issue with the Court during the upcoming Rule 16 conference.

# 17. We do not consent to the trial being conducted by a Magistrate Judge.

# 18. Identify any other issues to address at the Rule 16 Scheduling Conference.

The parties do not currently anticipate addressing any other issues not otherwise outlined in this Joint Discovery Plan at the Rule 16 Scheduling Conference.

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# **APPENDIX A**

	Current Deadline from <i>In re</i> <i>Metformin</i>	Plaintiffs' Proposed Dates	Defendants' Proposed Dates
Deadline to serve written discovery in County of Monmouth Only <sup>1</sup>	N/A	August 15, 2024	September 16, 2024
Deadline to serve third-party discovery, including service of subpoenas.	February 16, 2024 (6 Months Before Close of Fact)	September 30, 2024 (2.5 Months Before Close of Fact)	September 16, 2024 (4 Months Before Close of Fact)
Deadline for Substantial Completion of the Parties' Document Productions (90 Days Before Close of Fact Discovery)	May 15, 2024	September 16, 2024 (3 Months Before Close of Fact Discovery)	October 16, 2024 (3 Months Before Close of Fact Discovery)
Deadline to raise disputes concerning the number of depositions.	May 29, 2024 (3 Months Before Close of Fact)	Not Provided	October 30, 2024 (2.5 Months Before Close of Fact)
Deadline to raise discovery disputes (other than those arising during depositions).	May 2, 2024 (3.5 Months Before Close of Fact)	November 16, 2024 (1 Month Before Close of Fact)	October 30, 2024 (2.5 Months Before Close of Fact)
Deadline to file motions to add new parties or amend pleadings.	May 2, 2024	May 2, 2024, or 30 Days after MTD Ruling	May 2, 2024
Deadline to raise disputes concerning the number of depositions.	May 29, 2024 (2.5 Months Before Close of Fact)	October 30, 2024 (2.5 Months Before Close of Fact)	October 30, 2024 (2.5 Months Before Close of Fact)
Fact discovery ends.	August 15, 2024	December 16, 2024	January 16, 2025
Deadline for Plaintiffs to prepare and serve on Defendants any motion for class certification and accompanying expert reports.	August 29, 2024 (2-Weeks After Close of Fact)	February 14, 2025 (2 Months After Close of Fact)	January 31, 2025 (2-Weeks After Close of Fact)

<sup>&</sup>lt;sup>1</sup>As noted throughout the Joint Discovery Plan, Defendants' position is no new discovery should be served on Defendants given the expansive discovery underway in *In re Metformin*, and the anticipated consolidation of this matter with *In re Metformin* for discovery and pretrial purposes. Plaintiffs in *Metformin II* dispute that they are prohibited from seeking additional discovery given that there are new claims and allegations asserted in *Metformin II*.

Deadline for Defendants to depose Plaintiffs' expert witness pertaining to class certification.  Deadline for Defendants to prepare and serve on Plaintiffs any opposition to class certification and accompanying expert reports and Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification.	October 10, 2024 (1.5 Months After Prior Deadline)  November 11, 2024 (1 Month After Prior Deadline)	March 14, 2025 (1 Month After Prior Deadline)  April 14, 2025 (1 Month After Prior Deadline)	March 17, 2025 (1.5 Months After Prior Deadline)  April 16, 2025 (1 Month After Prior Deadline)
Deadline for Plaintiffs to depose	December 23, 2024	May 14, 2025	May 16, 2025
Defendants' expert witnesses	(~1 Month After	(1 Month After	(1 Month After
pertaining to class certification.	Prior Deadline)	Prior Deadline)	Prior Deadline)
Deadline for Plaintiffs to prepare and serve on Defendants any reply in support of any class certification motion, opposition to any Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification, and Rule 702 motions to exclude Defendants' expert witnesses pertaining to class certification.	January 20, 2025	June 16, 2025	June 16, 2025
	(1 Month After	(1 Month After	(1 Month After
	Prior Deadline)	Prior Deadline)	Prior Deadline)
Deadline for Defendants to prepare and serve on Plaintiffs their replies in support of any Fed. R. Evid. 702 motions to exclude Plaintiffs' expert witnesses pertaining to class certification and opposition to any Rule 702 motions to exclude Defendants' expert witnesses pertaining to class certification.	February 17, 2025	July 16, 2025	July 16, 2025
	(1 Month After	(1 Month After	(1 Month After
	Prior Deadline)	Prior Deadline)	Prior Deadline)

Deadline for Plaintiffs to prepare and serve on Defendants their replies in support of any Fed. R. Evid. motion to exclude Defendants' expert witnesses pertaining to class certification.	March 3, 2025	August 15, 2025	July 30, 2025
	(2 Weeks After	(1 Month After	(2 Weeks After
	Prior Deadline)	Prior Deadline)	Prior Deadline)
Deadline for Plaintiffs' counsel to assemble all motion papers and exhibits regarding class certification, and file them on the docket. Plaintiffs' counsel also shall provide two (2) courtesy copies of all motion papers to District Judge Madeline C. Arleo.	March 4, 2025	August 29, 2025	August 1, 2025
	(1 Day After Prior	(2 Weeks After	(2 Days After Prior
	Deadline)	Prior Deadline)	Deadline)

# **EXHIBIT 1**

## **EXHIBIT 1**

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